UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

Phyllis Rennells, Plaintiff, v. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center, a Massachusetts Corporation; Gregory A. Conigliaro; Barry J. Cadden, Lisa Conigliaro Cadden; GDC Properties Management, LLC, a Massachusetts Corporation; and ARL Bio Pharma, Inc., an Oklahoma Corporation, Defendants. _____/	)	Civil Action No:

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COMPLAINT AND JURY DEMAND

PARTIES AND JURISDICTION

1. Plaintiff PHYLLIS RENNELLS is a resident of Fowlerville, Livingston County, Michigan.

2. Defendant NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND COMPOUNDING CENTER (NECC) is a Massachusetts Corporation with its principle place of business at 697 Waverly Street, Framingham, Middlesex County,

Massachusetts. At all times relevant to this Complaint, Defendant NECC operated a "compounding pharmacy" and was purportedly engaged in the production and manufacture of custom pharmaceuticals.

3. Defendant GREGORY A. CONIGLIARO resides at 1 Mountain drive, Framingham, Massachusetts. He is a principal owner, Treasurer, Secretary, Vice President and Director of Defendant NECC. At the time of the actions giving rise to the Complaint, Defendant GREGORY A. CONIGLIARO was actively involved in the day-to-day operations of NECC.

4. Defendant BARRY J. CADDEN resides at 13 Manchester Drive, Wrentham, Massachusetts. He is a principal owner, President, Head Pharmacist, Vice President and Director of NECC. At the time of the actions giving rise to the Complaint, Defendant BARRY J. CADDEN was actively involved in the day-to-day operations of NECC and actively compounded drugs that were marketed and sold by NECC.

5. Defendant LISA CONIGLIARO CADDEN is the spouse of Defendant BARRY J. CADDEN and resides at 13 Manchester Drive, Wrentham, Massachusetts. She is a principal owner, board member and pharmacist at NECC. LISA CONIGLIARO CADDEN was actively involved in the day-to-day operations of NECC and actively compounded drugs that were marketed and sold by NECC.

6. Defendants GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN are also owners of several related entities, including Ameridose, LLC, Medical Sales Management, Inc., and Alaunus Pharmaceutical, LLC. Defendants GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN, together with other family members, have participated in the day to day operation and

management and serve as officers and directors of these related entities. These entities are related to NECC through common ownership and control, have utilized the same resources and fund sources, and currently or previously have been located in the same or adjoining facilities.

7. Defendant GDC PROPERTIES MANAGEMENT, LLC (GDC) is a Massachusetts limited liability corporation with a principle place of business at 701 Waverly Street, Framingham, Massachusetts. GDC's manager and registered agent is Defendant GREGORY A. CONIGLIARO. GDC owned and controlled the area of and surrounding NECC's compounding facility.

8. Defendant ARL BIO PHARMA, INC. (ARL) is an Oklahoma Corporation with its principle place of business at 840 Research Parkway, Ste. 546, Oklahoma City, Oklahoma. At all times relevant to this Complaint, Defendant ARL provided sterility and endotoxin testing to Defendant NECC for various prescription medications NECC produced.

9. This Court has federal question jurisdiction pursuant to 28 USC § 1332 as there is diversity between all Plaintiffs and all Defendants and, while the total amount of Plaintiff's damages are unknown and still accumulating, the amount in controversy exceeds $75,000.

10. 28 USC § 1391(b) and (c) make venue proper in this judicial district. Additionally, MDL Order No. 6, entered by this Court on June 28, 2013 in *In Re: New England Compounding Pharmacy, Inc. Product Liability Litigation*, MDL No. 1:13-md-2419-FDS makes venue proper in this Court.

GENERAL FACTUAL ALLEGATIONS

11. On or about September 26, 2012 Plaintiff PHYLLIS RENNELLS underwent lumbar epidural steroid injections at the facilities of Michigan Pain Specialists, PLLC. The injections were administered by Edward Washabaugh, III, M.D.

12. Both the operative report and the surgical inventory identify the steroid to be administered as "Depo-medrol." The billing likewise indicates that 80 mg of "Depo-medrol" was utilized in the September 26, 2012 procedure. Depo-medrol is the registered trade name of the drug methylprednisolone acetate (MPA) manufactured by Pfizer pharmaceuticals.

13. However, Plaintiff was not injected with Depo-medrol manufactured and sold by Pfizer pharmaceuticals. Instead she was injected with contaminated preservative-free MPA compounded and/or manufactured by Defendant NECC.

14. The preservative-free MPA injected into Plaintiff was obtained by Michigan Pain Specialists in a bulk transaction with Defendant NECC. It was not obtained with a patient-specific prescription.

15. The particular dose administered to Plaintiff was part of lot #06292012@26 produced by Defendant NECC. In documentation included with the invoice provided to Michigan Pain Specialists, Defendant ARL certified the lot as sterile and free from endotoxin.

16. There is nothing within Plaintiff's past medical history that contraindicates the use of Depo-medrol (i.e. MPA containing a preservative). Likewise, there is nothing within Plaintiff's past medical history that requires the use of a custom made preservative-free MPA in lieu of Depo-medrol.

17. In the month immediately following her injection at Defendant's facility with contaminated preservative-free MPA produced by Defendant NECC, Plaintiff began experiencing increasing pain in her lower back, at the injection site.

18. On October 13, 2012, Plaintiff presented to the emergency room of St. Joseph Mercy Hospital, Ann Arbor as the result of her increasing pain. A spinal tap was taken and came back negative for spinal meningitis.

19. Despite the negative result, Plaintiff continued to experience increasing pain in the her lower back, prompting St. Joe's to perform an MRI on October 28, 2012. That MRI revealed an epidural spinal abscess and, as a result of this finding, Plaintiff was admitted to the hospital.

20. Plaintiff remained hospitalized at St. Joseph Mercy Hospital, Ann Arbor until November 22, 2012. During her admission, she underwent an osterior multilevel bilateral decompressive laminectomy at L3-L4, L4-L5, and L5-SI with debridement and irrigation of her lumbar wound. The pathology report from the removed abscess revealed fungal involvement.

21. Plaintiff was also treated with various anti-fungal drugs. As the result of taking these drugs, Plaintiff suffered renal failure and cardiac events during her admission.

22. Plaintiff continues to treat for her fungal spinal infection on and outpatient basis at St. Joe's and continues to receive anti-fungal drugs, all of which have severe side effects.

23. The entirety of Plaintiff's post-injection complications, including the spinal abscess and fungal infection, were caused by contaminated preservative-free MPA produced by Defendant NECC, certified as sterile and free from endotoxin by Defendant

ARL, and administered by Michigan Pain Specialists, PLLC.

Defendant New England Compounding Center's History

24. NECC was created in 1998 by Defendants GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN, along with Douglas and Carla Conigliaro.

25. Defendant BARRY J. CADDEN and his spouse, LISA CONIGLIARO CADDEN, own 25 percent of the business, Carla Conigliaro owns 65 percent, and Defendant GREGORY A. CONIGLIARO owns 10 percent.

26. Defendant GREGORY A. CONIGLIARO also owns a recycling business located adjacent to NECC's facilities.

27. Defendant BARRY J. CADDEN was in charge of NECC's operations and a significant amount of compounding, including that of the contaminated lots preservative-free MPA at issue in the present action, occurred while he acted in this role.

28. In 1998, the Massachusetts Board of Registration in Pharmacy granted NECC a special pharmacy license. The license allowed Defendant NECC to operate as a compounding pharmacy.

29. The license allowed NECC to produce compounded pharmaceuticals without, but required the company to have an individual patient prescription for each compounded medication.

30. In February 2004, the Michigan Board of Pharmacy issued pharmacy and controlled substance licenses to NECC. These licenses allowed NECC to operate as a compounding pharmacy in Michigan.

31. Traditional pharmacy compounding is the combining or altering of ingredients

by a licensed pharmacist, in response to a licensed medical practitioner's prescription for an individual patient in order to produce a medication tailored to that patient's special medical needs. Compounding pharmacies, theoretically, create customized medications for patients who cannot use standardized medications as manufactured by the pharmaceutical industry.

32. In its simplest form, traditional compounding may involve reformulating a drug, for example, by removing a dye or preservative in response to a patient allergy, or changing the form of the drug, such as making a suspension or suppository dosage form for a patient that is unable to swallow.

33. In both Michigan and Massachusetts, compounding pharmacies must obtain a prescription for an individual patient in order to produce a compounded drug.

34. In 1997 federal law was modified to exempt drug compounding pharmacies from certain FDA oversight. In particular compounding pharmacies did not have to meet the premarket approval requirement for new drugs, did not have to comply with current good manufacturing practices in producing drugs, and did not have to provide adequate directions for their products' use. The trade-off was that compounding pharmacies could not mass produce drugs and could only supply facilities that provided patient-specific prescriptions.

35. From its inception, Defendant NECC's business practice was exploit the changes in federal law in order to tread the line between compounder and drug manufacturer. On one hand, it wished to reap profits by mass marketing the drugs it produced. On the other, it sought to avoid any and all FDA regulation whatsoever by labeling itself a "compounding pharmacy."

36. As soon as 1999, the Massachusetts Pharmacy Board investigated and warned NECC about the practice of including blank prescription forms in solicitations to doctors in violation of state law. Between 1999 and 2009, the board either investigated or warned NECC about similar practices on at least five other occasions.

37. In 2002, the United States Food and Drug Administration (FDA) investigated NECC when a physician reported that as many as five patients became ill following epidural injections of NECC compounded drugs.

38. In 2002, the FDA also received reports of at least two other individuals contracting bacterial meningitis after being injected with MPA produced by NECC. The ensuing investigation revealed bacterial contamination in sealed lots intended for sale and use. At least one lawsuit was filed against NECC as a result of these incidents.

39. In 2006, the FDA issued a formal Warning Letter to NECC. The Warning Letter detailed numerous problems at NECC including the sale of compounded drugs without patient-specific prescriptions, compounding copies of commercially available drugs, selling misbranded compounded drugs, and problems with storage and sterility. The letter has and continues to be available to the public.

40. In 2011, the Colorado Board of Pharmacy found NECC distributing compounded drugs without patient-specific prescriptions. The board issued a cease and desist letter to NECC in order to halt the practice.

41. The special dangers associated with drugs produced by compounding pharmacies have been known in the medical community for quite some time. A 2006 FDA study found contamination in 12 of the 36 samples it collected from compounding pharmacies. In 2007, the FDA published an article titled, “The Special Risks of Pharmacy

Compounding," highlighting numerous adverse events resulting from the use of compounded pharmaceuticals. The article further warned of the emergence of large scale compounding operations operating outside the bounds of traditional compounding practice.

42. The lack of FDA oversight was the origin of the medical community's concerns regarding compounding pharmacies.

43. Compounding pharmacies may voluntarily seek accreditation through the Pharmacy Compounding Accreditation Board. The International Academy of Compounding Pharmacists recommends that heath care providers assess whether or not a particular compounder is accredited before ordering drugs through it.

44. NECC has never been accredited by the Pharmacy Compounding Accreditation Board.

45. Even though compounding pharmacies are not required to obtain accreditation and avoid FDA oversight, they are still required to comply with standards established by U.S. Pharmacopeia, a private non-profit organization that sets quality control standards for the medical profession. In particular, U.S. Pharmacopeia chapter 797, "Pharmaceutical Compounding - Sterile Preparations," sets forth safety standards for compounding pharmacies.

46. Additionally, compounding pharmacies are not exempt from state laws or regulations governing the compounding and manufacture of prescription drugs.

47. NECC's practice of mass marketing and filling bulk orders of the prescription drugs it produced qualified it as a drug manufacturer under Michigan law at the time it distributed the tainted MPA to Michigan Pain Specialists. MCL 333.17706.

48. As NECC is a drug manufacturer under Michigan law, it must possess a

manufacturer's license separate and distinct from its pharmacy license in order to operate within the State. MCL 333.17748; Mich Admin Code, R 338.493a.

49. NECC has never operated with a drug manufacturer's license from the State of Michigan. Likewise, it has never been licensed as a drug manufacturer in any other jurisdiction.

2012 Spinal Meningitis Outbreak

50. On September 24, 2012 the Tennessee Department of Heath notified the Massachusetts Department of Public Health (DPH) about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. The Tennessee Department of Health noticed the cluster because of the rarity of fungal meningitis. All of the individuals diagnosed with fungal meningitis had received injections of preservative free MPA compounded by NECC.

51. On September 25, 2012 the Massachusetts DPH, Board of Registration in Pharmacy, and Bureau of Infectious Diseases convened a meeting with the Tennessee Department of Health, the U.S. Centers for Disease Control and Prevention (CDC), the FDA, and NECC. At the meeting, NECC produced documentation regarding the distribution of the three lots of preservative-free MPA suspected of causing the outbreak. According to the documentation, the suspected lots contained over 17,000 doses and were distributed to more than 14,000 patients in 23 states, including Michigan.

52. On September 26, 2012, NECC recalled three lots of preservative-free MPA it produced: lot #05212012@68, lot #06292012@26, and lot #08102012@51.

53. On September 26, 2012, Massachusetts DPH began investigating NECC's facility. When DPH arrived, investigators found NECC employees cleaning compounding

areas and conducting environmental testing. The investigators also saw signs of black contamination in compounding areas that were supposed to be sterile.

54. On October 1, 2012, DPH and the FDA began a joint investigation of NECC. Investigators were shown examples of MPA products that were labeled as patient-specific. NECC did not have individual prescriptions for these products. Instead, it produced lists of patients generated by a clinical facility and provided to NECC in order to obtain the product. NECC claimed the list of names was a proper prescription by the physician. This practice is not in accordance with Massachusetts and Michigan regulations.

55. During the inspection, the FDA observed greenish-black foreign matter in 83 out of 321 vials of preservative-free MPA produced by NECC, while 17 more showed what appeared to be white filamentous material. The FDA performed laboratory analysis on 50 additional vials of preservative-free MPA seized by NECC and found microbial growth in all 50 vials.

56. The investigation also revealed that NECC's own environmental monitoring system documented numerous instances between January and August 2012 where either bacteria or mold were detected in concentrations exceeding action-level thresholds.

57. As a result of the investigation, the FDA issued a "Form 483" report outlining several problems at NECC's facility. Documented problems included contamination in areas intended to be sterile. The form also indicates that NECC's HVAC units were within 100 feet of Defendant GREGORY A. CONIGLIARO'S waste recycling facility.

58. Defendant GDC owns the real property and improvements that housed both NECC's compounding facilities and the adjacent waste recycling facility owned by Defendant GREGORY A. CONIGLIARO.

59. On October 2, 2012 Massachusetts DPH voted to obtain a voluntary surrender of NECC's license or, if NECC would not voluntarily surrender its license, initiate action to suspend NECC's operation.

60. On October 3, 2012 NECC surrendered its Massachusetts pharmacy license, ceased production, and initiated a recall of all its products. NECC voluntarily surrendered its Michigan pharmacy and controlled substance licenses on December 12, 2102.

COUNT I: NEGLIGENCE - NECC DEFENDANTS

61. Plaintiff incorporates by reference all preceding paragraphs.

62. At all times, Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN owed a duty of care to Plaintiff, PHYLLIS RENNELLS, to exercise reasonable care in the compounding, preparation, production, manufacture, sale and/or, distribution of the medications they manufactured, including injectable preservative-free MPA, to ensure that they were reasonably safe, unadulterated, and free of contamination.

63. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN breached this duty and were negligent in that, among other things, they:

a. failed to maintain a clean and reasonably sterile environment in the areas where they compounded, prepared, produced, and/or manufactured medications, including preservative-free MPA, for use on patients and consumers, including Plaintiff;

b. failed to properly investigate incidents where mold or bacteria were detected in areas where they compounded, prepared, produced, and/or manufactured medications, including preservative-free MPA, for use on patients and consumers, including Plaintiff;

c. failed to undertake appropriate corrective actions when mold or bacteria were detected in areas where they compounded, prepared,

produced, and/or manufactured medications, including preservative-free MPA, for use on patients and consumers, including Plaintiff;

d. failed to prevent the contamination of the injectable preservative-free MPA that was ultimately administered to Plaintiff;

e. failed to prevent contaminated lots of injectable preservative-free MPA from entering the stream of commerce where it could potentially harm patients and consumers, including Plaintiff;

f. Failed to obtain proper licensing as a drug manufacturer in the State of Michigan.

64. As a direct and proximate result of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's negligence, Plaintiff was injected with contaminated preservative-free MPA compounded, prepared, produced, and/or manufactured by them.

65. As a direct and proximate cause of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's negligence Plaintiff has sustained the following damages and injuries:

a. She has developed fungal spinal abscess and other severe and debilitating conditions and injuries;

b. She has underwent numerous medical interventions including spinal surgery, extensive diagnostic studies and procedures, and a prolonged hospital admission;

c. She was required to take expensive medications, including Voriconazole, which have caused severe side effects, including renal failure, cardiac arrhythmia, nausea, hallucinations, and fatigue ;

d. She has suffered renal failure and cardiac events as the result of contracting a fungal spinal abscess and its subsequent treatment. She will be forced to take anti-coagulation drugs the rest of her life as a result of the cardiac events;

e. She has required extensive supportive care both in and out of the hospital;

f. She has incurred economic loss and substantial medical expenses;

g. She has suffered a loss of the natural enjoyment of life, including the ability to ambulate constant pain;

h. She has endured and will continue to endure protracted pain and suffering.

i. She has suffered several falls as a direct result of the side effects of her treatment. These falls have caused injury.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

COUNT II: GROSS NEGLIGENCE - NECC DEFENDANTS

66. Plaintiff incorporates by reference all preceding paragraphs.

67. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's actions as described herein constitute conduct so reckless, wilful and wanton as to demonstrate a substantial lack of concern as to whether an injury would occur.

68. As a direct and proximate result of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's gross negligence, Plaintiff was injected with contaminated preservative-free MPA compounded, prepared, produced, and/or manufactured by Defendants.

69. As a direct and proximate result of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's gross negligence, Plaintiff suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by

the trier of fact, together with interest costs and attorney fees.

COUNT III: MANUFACTURING DEFECT - NECC DEFENDANTS

70. Plaintiff incorporates by reference all preceding paragraphs.

71. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN compounded, prepared, produced, manufactured, packaged, labeled, marketed, sold and/or distributed injectable preservative-free MPA in a condition that was unreasonably dangerous in construction and/or composition, due to its propensity to cause injury when used by consumers, including Plaintiff.

72. The injectable preservative-free MPA was defective when it left the custody and control of Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN , in that it deviated in a material and significant way from similar products manufactured for the same or similar purpose and/or it deviated from Defendants' own manufacturing performance standards.

73. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN knew or should have known that it was reasonably foreseeable that the injectable preservative-free MPA could cause injuries and damage to consumers, including Plaintiff, when used int the normal course of commerce.

74. Despite the fact that Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN knew or should have known that the injectable preservative-free MPA was defective, Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN continued to market, label and sell the compound as a safe and effective product.

75. As a direct and proximate result of the use of injectable preservative-free

MPA compounded, prepared, produced, manufactured, packaged, labeled, marketed, sold and/or distributed by Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN, Plaintiff suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

COUNT IV: FAILURE TO WARN

76. Plaintiff incorporates by reference all preceding paragraphs.

77. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN compounded, prepared, produced, manufactured, packaged, labeled, marketed, sold, distributed and/or released into the stream of commerce injectable preservative-free MPA, including that used by or administered to Plaintiff.

78. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN had a duty to warn consumers, including Plaintiff, of the foreseeable risks associated with the use of injectable preservative-free MPA.

79. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN knew or should have known that it was foreseeable that the injectable preservative-free MPA compounded, prepared, produced, manufactured, packaged, labeled, marketed, sold, distributed and/or released into the stream of commerce by Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN , including that used by or administered to Plaintiff, could

cause illness.

80. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN failed to timely and properly warn consumers, including health care professionals who would administer the preservative-free MPA, of material facts regarding the safety and efficacy of the product.

81. Had Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN properly warned consumers, including health care professionals who would administer the preservative-free MPA, of the true facts, such warnings would have been heeded and no consumer or health care professional would have administered or used the injectable preservative-free MPA.

82. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN failed to timely and properly provide consumers, including health care professionals who would administer the preservative-free MPA, post-marketing warnings, instruction, and/or training when Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN knew or should have known that the injectable preservative-free MPA they compounded, prepared, produced, manufactured, packaged, labeled, marketed, sold, distributed and/or released into the stream of commerce was likely to cause illness.

83. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN failed to perform or cause to be performed adequate testing or other remedial measures to make the injectable preservative-free MPA safe for use, and in fact suppressed and/or concealed data and/or evidence that would have disclosed the true facts regarding the product.

84. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's actions were taken in reckless disregard of the safety and health of consumers, including Plaintiff, who were injected with contaminated preservative-free MPA.

85. As a direct and proximate result of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's failure to warn, Plaintiff was injected with contaminated preservative-free MPA compounded, prepared, produced, and/or manufactured by them.

86. As a direct and proximate result of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's failure to warn, Plaintiff suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

COUNT V: BREACH OF EXPRESS AND IMPLIED WARRANTIES - NECC DEFENDANTS

87. Plaintiff incorporates by reference all preceding paragraphs.

88. At all relevant times, Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN expressly and implicitly represented and warranted to consumers and health care professionals who would administer the injectable preservative-free MPA that it was safe, unadulterated or contaminated, and fit for its intended use.

89. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's actions rendered the injectable preservative-free MPA unfit

for its intended use and unsafe.

90. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's actions constitute a breach of the express and implied warranties they made regarding the efficacy of their injectable preservative-free MPA to consumers and health care professionals who would administer the product.

91. As a direct and proximate result of Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's breach of express and implied warranties, Plaintiff was injected with contaminated preservative-free MPA compounded, prepared, produced, and/or manufactured by them.

92. As a direct and proximate result of Defendants' breach of express and implied warranties, Plaintiff suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

COUNT VI: CIVIL CONSPIRACY - NECC DEFENDANTS

93. Plaintiff incorporates by reference all preceding paragraphs.

94. Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN acted in concert with Michigan Pain Specialists, PLLC, to fill bulk orders of compounded preservative-free MPA without individual patient prescriptions.

95. This practice allowed Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN to approach the sales volumes

of FDA approved drug manufactures while still operating a compounding pharmacy outside of FDA oversight.

96. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's practice of compounding and filling bulk orders of preservative-free MPA without individual patient prescriptions violated the conditions of its Massachusetts and Michigan pharmacy licenses as well as state and federal regulations governing compounding pharmacies.

97. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's practices also qualified them as drug manufacturers under Michigan law.

98. Despite acting as drug manufacturers under Michigan law, Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN never obtained a drug manufacturer's license from the State of Michigan.

99. Defendant NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN's failure to obtain the necessary drug manufacturer's license directly violates Michigan law.

100. Likewise Michigan Pain Specialists, PLLC's practice of obtaining preservative-free MPA in bulk from Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN likewise violated state and federal regulations regarding the procurement of medications from compounding pharmacies.

101. As a direct result of the unlawful and concerted action taken by Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN and Michigan Pain Specialists, PLLC, Plaintiff was negligently injected with

contaminated preservative-free MPA.

102. As a direct and proximate cause of the conspiracy between Defendants NECC, GREGORY A. CONIGLIARO, BARRY J. CADDEN, and LISA CONIGLIARO CADDEN and Michigan Pain Specialists, PLLC, to supply purportedly individualized compounded medications in a bulk manner, Plaintiff suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendant for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

COUNT VII: NEGLIGENCE - ARL BIO PHARMA, INC.

103. Plaintiff incorporates by reference all preceding paragraphs.

104. At all times, Defendant ARL owed a duty of care to Plaintiff, PHYLLIS RENNELLS, to exercise reasonable care in the analysis and certification of the subject batch of injectable preservative-free MPA manufactured by Defendant NECC.

105. Defendant ARL breached this duty and was negligent in that, among other things, it:

a. failed to meet U.S. Pharmacopeia standards in the testing of the subject lot despite purporting to do so;

a. failed to test an adequate sample size of the subject lot in order to obtain an acceptable confidence rate as to its sterility;

b. certified the subject lot as “sterile” when, in fact, it was contaminated;

106. As a direct and proximate result of Defendant ARL’s negligence, Plaintiff was injected with contaminated preservative-free MPA.

107. As a direct and proximate cause of Defendant ARL’s negligence, Plaintiff

suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendant for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

COUNT VIII: PUBLIC NUISANCE - GDC PROPERTIES MANAGEMENT, LLC

108. Plaintiff incorporates by reference all preceding paragraphs.

109. At all relevant times, Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, or GDC were in control of the property and improvements at Defendant NECC's compounding facility located at 697 Waverly Street, Framingham, Massachusetts.

110. At all relevant times, Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, or GDC were also in control of the property and improvements at the waste recycling facility adjacent to Defendant NECC's compounding facility.

111. Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC knew that Defendant NECC was compounding preservative-free MPA at is 697 Waverly Street address.

112. Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC knew that the adjacent waste recycling plant was operating within 100 feet of Defendant NECC's HVAC units.

113. Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC knew that the facilities used by Defendant NECC were unsuitable for use as a compounding facility, yet continued to lease said premises to Defendant NECC for that purpose.

114. Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, or GDC owed

Plaintiff, PHYLLIS RENNELLS, a duty to maintain the property and improvements at both the NECC facility and the adjacent waste recycling facility in a condition that minimized the risk of fungal contamination on the premises.

115. Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, or GDC breached this duty and were negligent in that, among other things, they:

a. Allowed the waste recycling facility to operate within 100 feet of Defendant NECC's HVAC units.

b. Allowed the premises to deteriorate in a manner that increased the likelihood of contamination to Defendant NECC's products.

116. In allowing such conditions to exist on their premises Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC unreasonably and significantly interfered with the public health and safety.

117. In allowing such conditions to exist on their premises Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC unreasonably and significantly interfered with the public right expressed in Massachusetts law, specifically 247 CMR 6.02(1).

118. The public nuisance caused by Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC has caused Plaintiff, PHYLLIS RENNELLS special injury in that she has sustained significant injury to her personal health.

119. As a direct and proximate cause of the public nuisance caused by Defendants BARRY J. CADDEN, GREGORY A. CONIGLIARO, and GDC, Plaintiff suffered the injuries and damages set forth in paragraph 65 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by

the trier of fact, together with interest costs and attorney fees.

COUNT IX: VIOLATION OF THE MICHIGAN CONSUMER'S PROTECTION ACT

120. Plaintiff incorporates by reference all preceding paragraphs.

121. Plaintiff is a person within the meaning of the Michigan Consumer's Protection Act (MCPA).

122. At all relevant times, Defendants were conduction trade or commerce within the meaning of the MCPA.

123. Defendants have engaged in the following unfair trade and business practices as defined in the MCPA:

a. Causing a probability of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods in violation of MCL 445.903(a);

b. Representing that goods have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have in violation of MCL 445.903(c);

c. Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another, in violation of MCL 445.903(e);

d. Causing a probability of confusion or misunderstanding as to the legal rights, obligations, or remedies of a party to the transaction in violation of MCL 445.903(n);

e. Failing to reveal facts material to the transaction, the omission of which tends to mislead or deceive the consumer, and which facts could not have reasonably been known by the consumer in violation of MCL 445.903(s);

f. Failing to provide the promised benefits to the transaction in violation of MCL 445.903(y);

g. Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is, in violation of MCL 445.903(bb);

h. Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner in violation of MCL 445.903(cc).

124. As a direct and proximate cause of Defendants' violation of the MCPA, Plaintiff suffered the injuries and damages set forth in paragraph 63 above.

WHEREFORE, Plaintiff PHYLLIS RENNELLS respectfully demand judgment against the above named Defendants for whatever amount she is found to be entitled by the trier of fact, together with interest costs and attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, PHYLLIS RENNELLS prays for judgment against each Defendant, jointly and severally, as follows:

1. For actual damages as established by proof;
2. For compensatory past, present, and future damages in excess of $75,000, and in an amount to fully compensate Plaintiff, as permitted by law;
3. For consequential damages as permitted by law;
4. For statutory damages as permitted by law;
5. For punitive damages as permitted by law;
6. For interest, attorney fees, costs, and expenses as permitted by law;
7. For such other relief as is just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff, PHYLLIS RENNELLS hereby demands a trial by jury of the above entitled matter with respect to all issues so triable.

RAVID AND ASSOCIATES, P.C.

By: /s/Keith M. Banka

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Dated: October 24, 2013